REMARKS/ARGUMENT

Claim Amendments

Claim 1 has been amended to define the composition of matter as comprising PS and an oil base, wherein the PS is predominantly in the form of its salt with a divalent metal cation, which salt is dispersed in the oil base.

Support for a divalent salt of PS may be found, for example, in the paragraph bridging pages 5 and 6 of the PCT publication, and at line 2 of the last paragraph of page 14 of the PCT publication. Support for an oil base may be found, for example, in original claim 13. Support for the salt being dispersed in the oil base may be found, for example, in original claim 13.

Claim 8 has been amended. Support for calcium and magnesium salts may be found, for example, at line 2, page 6 of the PCT publication.

Support for new claim 53 may be found, for example, in original claim 15.

Support for new claim 54 may be found, for example, in original claim 27.

Support for new claim 55 may be found, for example, in original claim 21.

Support for new claim 56 may be found, for example, in original claim 24.

Support for new claim 57 may be found, for example, in original claim 24.

Claims 3, 4, 6, 7, 9-13, 16, 18, 19, 22, 23, 25, 26, 28, 29, 31, 32 and 34-52 were

cancelled without prejudice.

Remaining claims were amended to conform to claim 1.

It is respectfully submitted that no new matter has been added.

Applicant's submissions

General

The present amendment is supplemental to the amendment submitted on June 30, 2009.

Without conceding to any of the Examiner's rejections, this amendment is submitted in order to expedite prosecution of the application.

The claims were amended, as detailed above, and the set of claims now relates to a specific embodiment of the invention – a composition of matter comprising salt of phosphatidylserine (PS) with a divalent cation, particularly the calcium and magnesium salts, dispersed in an oil base, particularly medium-chain triglycerides, capsules comprising this composition of matter, and the various uses thereof.

Experimental evidence

Applicant respectfully submits herewith a declaration by one of the inventors. As detailed in the declaration the storage stability of PS in accordance with the invention, contained in capsules, was tested for storage under mild (ambient) and extreme (accelerated) conditions (Part 1). In addition, the storage stability of PS in accordance

with the invention, contained in capsules, was compared with the storage stability of commercially available PS (by Manufacturer A), claimed to be "stable", contained in capsules, (Part 2 and Figure 2).

As shown in the Part 1 of the declaration, PS composition of matter as defined in amended claim 1, contained in soft gel capsules, exhibited long storage stability under mild (ambient) and extreme ("accelerated") storage conditions. Remarkably, the PS in the capsules in accordance with the invention did not degrade even after 12 months of storage at extreme conditions, and 24 months at ambient, normal storage conditions (Part 1 of the declaration, figure 1 and Table 1).

Part 2 of the declaration shows that the PS soft gel capsules in accordance with the invention were considerably more stable than the commercial "stable" PS capsules.

Analysis of the PS contained in the capsules showed that the PS in accordance with the invention was predominantly in the form of a salt with a divalent metal cation (mostly the calcium salt), while the other capsule (Supplier A's) contained PS which was mostly in the form of monovalent salt(s) (sodium and potassium salts).

Novelty

The Examiner, in the last Official Action, stated that the instant application claims a composition of matter comprising from about 1 to about 99% (w/w) phosphatidylserine. The Examiner rejected Claims 1, 3-8, 18 and 42-44 under 35 U.S.C. 102(b) as being anticipated by Buchholz et al. (US Patent No. 6514973, cited on PTO Form 1449). According to the Examiner, Buchholz et al. exemplify a composition consisting of phosphatidylserine, choline, S-adenosyl methionine, serine, and L-5-methyltetrahydro-

folic acid. The amount of phosphatidylserine is 9% based on the total weight of the composition. It is taught that component A is phosphatidylserine and their physiologically acceptable salts (column 4, lines 37-40). Physiologically acceptable salts include sodium, potassium, magnesium, calcium, ammonium and substituted ammonium salts (column 5, lines 17-24). Buchholz et al. do not exemplify the salt form of the phosphatidylserine. There are only two choices for the phosphatidylserine, the free base or the salt form. Therefore, according to the Examiner, one of ordinary skill in the art can immediately envision utilizing the salt form of the phosphatidylserine.

Applicant respectfully traverses.

With reference to previously submitted arguments, present amendments and the experimental evidence submitted herewith, claim 1 has been amended as above stated, and is directed to a composition of matter comprising PS and an oil base, wherein the PS is predominantly in the form of a divalent salt, particularly calcium, which is dispersed in the oil base. This specific composition of matter is novel over Buchholz et al. It is to be noted that the PS composition of matter of claim 1 exhibits such storage stability that no more than about 1 to about 5% of the PS are decomposed after a storage period of at least 6 months.

Buchholz et al. does not specifically disclose a PS calcium or magnesium salt, neither does it disclose such PS divalent salt dispersed in an oil base. Buchholz et al. also does not specifically disclose a capsule containing a dispersion of a divalent salt of PS in oil.

As already presented in the last amendment, the specification (see, e.g. page 2, last paragraph) explains that one of the main problems associated with PS preparations, especially in liquid form, is their low stability, due to rapid decomposition. The rapid decomposition changes the structure of phosphatidylserine (removes the serine head

group) causing loss of activity. The inventors of the present application have succeeded in preparing storage stable PS compositions, which maintain at least 95% of the PS after long storage, as shown in the application and in the attached Declaration.

The annexed Declaration clearly shows the improved storage-stability of the claimed PS composition, considerably superior to the stability of commercially available compositions, even those commercial compositions that claim to be storage-stable.

According to Buchholz et al., the PS to be used is a commercially available product (see Col. 7, lines 4-5), and thus comparable to the commercial product tested in the comparative example of the Declaration. Applicant found that PS in the form of a dispersion of its divalent salt in oil has substantially improved storage stability compared to commercially available PS preparations.

Thus, although Buchholz mentions that the active ingredients, including PS, can be in the form of their physiologically acceptable salts, including alkaline earths salts, including calcium and magnesium salts, this prior art document does not specifically describe a salt of PS with a divalent cation, neither a PS calcium or magnesium salt. When reading Buchholz et al, one has to guess which cation may be suitable for which of the active ingredients, namely, phosphatidylserine (or methyl or methylene donor), with a vast number of combinations possible. The document does not describe any specific combination of cation-anion, let alone divalent cation-PS anion.

Furthermore, while Buchholz et al mentions that vegetable oils can be used as excipient, it does not generally or specifically describe a composition of matter comprising an oil, specifically not a dispersion of a specific salt of PS in oil.

It is therefore respectfully submitted that Buchholz et al does not destroy the novelty of

the PS composition of matter of claim 1.

Inventive step

Buchholz et al is also not relevant to the inventive step of the claimed PS composition of matter.

As already mentioned, it would take an extreme amount of experimentation to arrive at the specific divalent salt of PS from the description in Buchholz et al. The man of skill in the art reading the cited document, would not know whether to use a salt of PS, or only of the other ingredients (e.g. methyl or methylene donor), and even if electing PS, there is a vast number of possible cations. Even if choosing the specific form of divalent PS salt, particularly calcium and/or magnesium, the cited document does not give the man of skill in the art any guidance to use these particular PS salts dispersed in oil. Within the framework of Buchholz et al, each such salt would not only have to be prepared and tested for solubility, availability, etc., but also for compatibility with each of the other active principals therein.

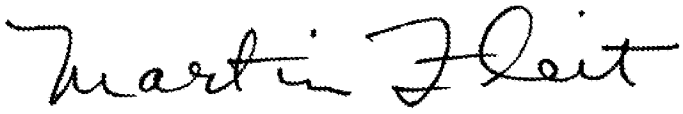
Particularly in view of the improved storage stability of the specific salts claimed in the amended claims of the present application, when dispersed in oil, as shown in the attached Declaration, it is respectfully submitted that Buchholz et al does not describe, does not even suggests, the composition of matter of the invention, and does not destroy the inventive step therein.

None of the other references cited remedies the lack of any specific teaching in Buchholz et al regarding the invention now recited in the amended claims. It is therefore respectfully submitted that the invention recited in the amended claims has an inventive step for which the cited documents have no disclosure or teaching.

In light of the foregoing remarks, this application, with the amended claims, should be in condition for allowance, and early passage of this case to issue is earnestly solicited. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7056-X08-020).

Respectfully submitted,



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Attachment: Declaration